Complete Summary

GUIDELINE TITLE

Screening for type 2 diabetes mellitus to prevent vascular complications: updated recommendations from the Canadian Task Force on Preventive Health Care.

BIBLIOGRAPHIC SOURCE(S)

Feig DS, Palda VA, Lipscombe L. Screening for type 2 diabetes mellitus to prevent vascular complications: updated recommendations from the Canadian Task Force on Preventive Health Care. CMAJ 2005 Jan 18;172(2):177-80. [44 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a precious version: Canadian Task Force on Preventive Health Care. Canadian Task Force on the Periodic Health Examination. Canadian Guide to Clinical Preventive Health Care. Ottawa (Canada): Health Canada; 1994. Screening for diabetes mellitus in the non-pregnant adult. p. 602-9.

A complete list of planned reviews, updates, and revisions is available under the What's New section at the <u>Canadian Task Force on Preventive Health Care</u> (CTFPHC) Web site.

COMPLETE SUMMARY CONTENT

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BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

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IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Type 2 diabetes mellitus

GUIDELINE CATEGORY

Prevention Screening Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Internal Medicine
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

- To update the 1994 recommendations of the Canadian Task Force of Preventive Health care for screening for type 2 diabetes mellitus
- To make recommendations regarding screening and treatment to prevent the progression of type 2 diabetes mellitus and improve health outcomes

TARGET POPULATION

- Asymptomatic adults
- Asymptomatic adults with hypertension or hyperlipidemia
- Asymptomatic adults with impaired glucose tolerance

INTERVENTIONS AND PRACTICES CONSIDERED

Prevention/Screening

- 1. Fasting glucose test
- 2. Oral glucose tolerance test (OGTT)

Treatment

- 1. Lifestyle interventions (e.g., diet, exercise)
- 2. Medication
 - Metformin
 - Acarbose

MAJOR OUTCOMES CONSIDERED

- Glucose levels, blood pressure readings
- Progression to diabetes
- Cardiovascular events
- Diabetes mellitus-related morbidity and mortality

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

In developing these recommendations, the Canadian Task Force on Preventive Health Care (CTFPHC) drew heavily on a recent systematic review prepared for the US Preventive Services Task Force (USPSTF) of the evidence for screening asymptomatic people for type 2 diabetes mellitus to prevent cardiovascular events. That review was enhanced by the CTFPHC in 2 ways: all new literature on screening was incorporated, and a separate systematic review of the evidence related to the prevention of diabetes in people with impaired glucose tolerance was undertaken.

Literature Search

The literature from the USPSTF review of screening for type 2 diabetes mellitus from 1996 was reviewed, and MEDLINE and the Cochrane library from January 1, 1994 to July 30 2002 were searched. The CTFPHC updated a similar search of the literature from July 30, 2002 to December 31, 2002.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Research Design Rating

- I: Evidence from well-designed randomized controlled trial(s)
- II-1: Evidence from well-designed controlled trial(s) without randomization

- II-2: Evidence from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group
- II-3: Evidence from comparisons between times or places with or without the intervention; dramatic results from uncontrolled studies could be included here
- III: Opinions of respected authorities, based on clinical experience; descriptive studies or reports of expert committees

Quality Rating

Good: A study (including meta-analyses or systematic reviews) that meets all design- specific criteria* well

Fair: A study (including meta-analyses or systematic reviews) that does not meet (or it is not clear that it meets) at least one design-specific criterion* but has no known "fatal flaw"

Poor: A study (including meta-analyses or systematic reviews) that has at least one design-specific* "fatal flaw", or an accumulation of lesser flaws to the extent that the results of the study are not deemed able to inform recommendations

*General design-specific criteria are outlined in Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow CD, Teutsch SM, Atkins D. Current Methods of the U.S. Preventive Services Task Force: A Review of the Process. Am J Prev Med 2001; 20(suppl 3): 21-35.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Critical Appraisal

The Task Force reviewed 1) the initial analytic framework and key questions for the proposed review; 2) the subsequent draft(s) of the complete manuscript providing critical appraisal of the evidence prepared by the lead authors, including identification and double, independent critical appraisal of key studies or recent systematic reviews, and ratings of the quality of this evidence using the task force's established methodological hierarchy; and 3) a summary of the evidence and proposed recommendations.

Consensus Development

Evidence for this topic was presented by the lead author(s) and deliberated upon during task force meetings in February, June, and October 2003. Expert panelists addressed critical issues, clarified ambiguous concepts and analyzed the synthesis of the evidence. At the end of this process, the specific clinical recommendations proposed by the lead author were discussed, as were issues related to clarification of the recommendations for clinical application and any gaps in evidence. The results of this process are reflected in the description of the decision criteria presented with the specific recommendations. The group and lead author(s) arrived at final decisions on recommendations unanimously.

Procedures to achieve adequate documentation, consistency, comprehensiveness, objectivity, and adherence to the task force methodology were maintained at all stages during review development, the consensus process and beyond to ensure uniformity and impartiality throughout.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations Grades for Specific Clinical Preventive Actions

- A: The Canadian Task Force (CTF) concludes that there is good evidence to recommend the clinical preventive action.
- B: The CTF concludes that there is fair evidence to recommend the clinical preventive action.
- C: The CTF concludes that the existing evidence is conflicting and does not allow making a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making.
- D: The CTF concludes that there is fair evidence to recommend against the clinical preventive action.
- E: The CTF concludes that there is good evidence to recommend against the clinical preventive action.
- I: The CTF concludes that there is insufficient evidence (in quantity and/or quality) to make a recommendation; however, other factors may influence decision-making.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Peer Review

Subsequent to the Task Force meetings, the lead authors revised the manuscript accordingly. After final revision, the Task Force sent the manuscript to a number of experts in the field (identified by Task Force members at the meeting). Feedback from these experts was incorporated into a subsequent draft of the manuscript.

Recommendations of Others

Recommendations for screening for type 2 diabetes in adults from the following groups were discussed: the Canadian Diabetes Association; the American Diabetes Association, and the US Preventive Services Task Force.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendation grades [A-E] and levels of evidence [I, II-1, II-2, II-3, III, good, fair, poor] are indicated after each recommendation. Definitions for these grades and levels are provided at the end of the "Major Recommendations" field.

The Canadian Task Force on Preventive Health Care (CTFPHC) concludes that there is fair evidence to recommend screening patients with hypertension for type 2 diabetes to reduce the incidence of cardiovascular (CV) events and CV mortality (B recommendation). (Harris & Eastman, 1998 [I, fair]; UK Prospective Diabetes Study (UKPDS) 38, 1998 [I, fair]; Schrier et al., 2002 [I, fair]; Estacio et al., 2000 [I, fair])

The CTFPHC concludes that there is fair evidence to recommend screening patients with hyperlipidemia for type 2 diabetes to reduce the incidence of CV events (B recommendation). (Pyorala et al., 1997 [I, good]; Koskinen et al., 1992 [I, good]; Frick et al., 1987 [I, good]; "Prevention of cardiovascular events," 1998 [I, good]; Downs et al., 1998 [I, good]; Rubins et al., 1999 [I, good]; Haffner et al., 1999 [I, good]; Pignone et al., 2001 [I, good]; MRC/BHF Heart Protection Study, 2002 [I, good]; Robins, 2001 [I, good]; Goldberg et al., 1998 [I, good])

The CTFPHC concludes that there is good evidence to recommend treatment of impaired glucose tolerance (IGT) with lifestyle interventions to reduce the incidence of diabetes progression (B recommendation). (Pan et al., 1997 [I, good]; Tuomilehto et al., 2001 [I, good]; Knowler et al., 2002 [I, good])

The CTFPHC concludes that there is insufficient evidence to recommend treatment of IGT with metformin or acarbose to reduce the incidence of diabetes

progression (I recommendation). (Chiasson et al., 2002 [I, fair]; Knowler et al., 2002 [I, fair]; Diabetes Prevention Program Research Group, 2003 [I, fair])

The CTFPHC concludes that there is fair evidence to recommend treatment of IGT with acarbose to prevent CV events or hypertension (B recommendation). (Chiasson et al., 2003 [I, fair])

Clinical Considerations

In patients who do not meet the above criteria, the decision to screen for diabetes or impaired glucose tolerance may be made on an individual basis. The decision to screen should hinge on an estimate of the patient's overall risk of cardiovascular disease (CVD). Patients whose overall risk would be raised by a diagnosis of diabetes to the extent that treatment would be changed (i.e., if the overall risk of CVD is raised to more than 10%) may merit screening. Patients with other known CVD risk factors (e.g., smoking or increased age) may also benefit from screening for diabetes.

Screening involves only patients who are asymptomatic. Those who exhibit symptoms or signs of diabetes or those who have potential complications associated with diabetes should receive diagnostic testing.

Screening is best accomplished with a fasting plasma glucose test. Diabetes is diagnosed if the fasting plasma glucose level is 7.0 mmol/L or greater, or if the plasma glucose level is 11.1 mmol/L or greater in a 2-hour oral glucose tolerance test (OGTT). Either test should be done on 2 occasions before a diagnosis can be made. Impaired fasting glucose is diagnosed if the fasting glucose level is 6.1-6.9 mmol/L, and impaired glucose tolerance is diagnosed if the plasma glucose level is 7.8-11.0 mmol/L in a 2-hour OGTT.

There is no information regarding the optimal screening frequency.

Definitions:

Levels of Evidence

Research Design Rating

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- E: The CTF concludes that there is good evidence to recommend against the clinical preventive action.
- I: The CTF concludes that there is insufficient evidence (in quantity and/or quality) to make a recommendation; however, other factors may influence decision-making.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Maneuver: Screening patients with hypertension for type 2 diabetes to reduce the incidence of cardiovascular (CV) events and CV mortality

• Level of Evidence: I, fair (4 randomized controlled trials [RCTs])

Maneuver: Screening patients with hyperlipidemia for type 2 diabetes to reduce the incidence of CV events

Level of Evidence: I, good (11 RCTs)

Maneuver: Treating overweight people with impaired glucose tolerance (IGT) with lifestyle intervention to reduce the incidence of diabetes progression

• Level of Evidence: I, good (3 RCTs)

Maneuver: Treating overweight people with IGT with acarbose or metformin to reduce diabetes progression.

• Level of Evidence: I, fair (3 RCTs)

Maneuver: Treating overweight people with IGT with acarbose to reduce CV events and hypertension.

• Level of Evidence: I, fair (1 RCT)

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Benefits of Screening

There is no direct evidence that screening for diabetes in the preclinical phase leads to benefit. Although there is good (level I) evidence that treatment with tight glycemic control in patients who have a clinical diagnosis of diabetes decreases the progression of microvascular complications after 10 years of treatment, benefits were seen only in intermediate outcomes (i.e., decreased progression of retinopathy and nephropathy), with a nonsignificant trend toward decreased rates of myocardial infarction. Health outcomes such as death, cardiovascular events, blindness, end-stage renal disease, and amputations were not reduced.

Therefore, early detection of diabetes through screening 5-6 years before clinical symptoms emerge in order to treat with tight glycemic control may not have a substantial incremental benefit over clinical diagnosis. With screened patients, presumably the gain during the first 15 years would be similar to or even less than that seen in diagnosed patients, given that their level of hyperglycemia would be milder in most cases. One could expect that the benefit might be translated into improved health outcomes in trials of longer duration. Improved

health outcomes might also be demonstrated if treatment were started sooner; however, there is no evidence indicating this currently.

There is good (level I) evidence that treatment of hypertension and hyperlipidemia in patients with diabetes decreases the incidence of cardiovascular events and cardiovascular-related death (macrovascular complications) within 5 years. Therefore, if one extrapolates this evidence to a screened population, early identification of diabetes in patients with hypertension or hyperlipidemia, and aggressive treatment, would have a substantial early benefit.

A targeted approach of screening only patients with hypertension or hyperlipidemia provides more certain benefit. In addition, it subjects fewer people to potential harms than does screening a broader population, because the number needed to screen in order to prevent 1 cardiovascular event over 5 years in a population with hypertension or hyperlipidemia is substantially lower than the number in the general population.

Screening for Impaired Glucose Tolerance

Although there are studies suggesting a benefit of treating people who have impaired glucose tolerance to reduce the incidence of progression of diabetes and possibly cardiovascular disease, the evidence is still inadequate to recommend screening for impaired fasting glucose or impaired glucose tolerance. However, people with the latter condition may nonetheless be identified in the course of their health care. These patients should be treated with lifestyle interventions aimed at lowering weight and increasing exercise, because such interventions may lower the incidence of diabetes (level I evidence). Acarbose treatment can also be considered for these patients, because it has been shown to reduce the incidence of cardiovascular outcomes and hypertension (level I evidence). Although the use of metformin and acarbose in patients with impaired glucose tolerance has been shown to reduce the incidence of diabetes over 3 years, the rate of diabetes dropped when metformin was discontinued. Of note, the prevention trials were all of 3 to 6 years' duration, and it is unclear whether the effects of lifestyle or pharmacologic intervention persist beyond that period. Furthermore, it is still uncertain whether diabetes can truly be prevented or whether these strategies simply delay its onset. The impact of delaying diabetes for a few years on preventing microvascular complications would likely be small, since the risk of complications is low in the first 15 years after diabetes diagnosis. The beneficial effects of lifestyle modification on cardiovascular events in people with impaired glucose tolerance also remain to be demonstrated. Finally, the cost-effectiveness of screening for impaired glucose tolerance and offering lifestyle interventions only to those with a positive test result and not to all people with diabetes risk factors has not been examined.

POTENTIAL HARMS

There has been little direct assessment of the potential harmful effects of screening for diabetes, and no decrease in quality of life has been associated with screening. The potential but unresearched harms of screening may include labelling, anxiety and altered self-perception, and loss of insurability. It has been estimated that in at least 30% of people who have positive impaired glucose

tolerance or impaired fasting glucose test results, glucose levels revert to normal and diabetes never develops.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The Canadian Task Force on Preventive Health Care (CTFPHC) recognizes that in many cases, patient-specific factors need to be considered and discussed, such as the value the patient places on the clinical preventive action; its possible positive and negative outcomes; and the context and/or personal circumstances of the patient (medical and other). In certain circumstances where the evidence is complex, conflicting, or insufficient, a more detailed discussion may be required.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Quick Reference Guides/Physician Guides

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Feig DS, Palda VA, Lipscombe L. Screening for type 2 diabetes mellitus to prevent vascular complications: updated recommendations from the Canadian Task Force on Preventive Health Care. CMAJ 2005 Jan 18;172(2):177-80. [44 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1994 (revised 2005 Jan 18)

GUI DELI NE DEVELOPER(S)

Canadian Task Force on Preventive Health Care - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

The Canadian Task Force on Preventive Health Care (CTFPHC) is funded by Health Canada.

GUIDELINE COMMITTEE

Canadian Task Force on Preventive Health Care (CTFPHC)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Competing interests: none declared for Valerie Palda or Lorraine Lipscombe. Denice Feig has received research funding from Novo Nordisk and an unrestricted educational grant from Aventis Pharma.

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A complete list of planned reviews, updates, and revisions is available under the What's New section at the <u>Canadian Task Force on Preventive Health Care</u> (CTFPHC) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>Canadian Task Force on Preventive Health</u> <u>Care (CTFPHC) Web site</u>.

Print copies: Available from Canadian Task Force on Preventive Health Care, Clinical Skills Building, 2nd Floor, Department of Family Medicine, University of Western Ontario, London, Ontario N6A 5C1, Canada.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Stachenko S. Preventive guidelines: their role in clinical prevention and health promotion. Ottawa: Health Canada, 1994. Available from the "History & Methods" section of the <u>Canadian Task Force on Preventive Health Care</u> (CTFPHC) Web site.
- CTFPHC history/methodology. Ottawa: Health Canada, 1997. Available from the "History & Methods" section of the CTFPHC Web site.
- Quick tables of current recommendations. Ottawa: Health Canada, 1997. Available from the CTFPHC Web site.
- Feig, D.S., Lipscombe, L.L., Palda, V.A., and the Canadian Task Force on Preventive Health Care. Screening for Type 2 diabetes to prevent vascular complications: updated recommendations from the Canadian Task Force on Preventive Health Care. CTFPHC Technical Report. November 2003. London, ON: Canadian Task Force. Available from the CTFPHC Web site.
- Feig, D.S., Lipscombe, L.L., Palda, V.A., and the Canadian Task Force on Preventive Health Care. Preventive Health Care, 2005: screening for type 2 diabetes mellitus to prevent vascular complications. Recommendation table. Available from the CTFPHC Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 7, 2005. The information was verified by the guideline developer on April 26, 2005.

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Date Modified: 10/9/2006